

09/705,579

REMARKS

Claims 42, 44, 55, 63 and 65 are rejected under 35 USC Section 103(a) as being unpatentable over Hudziak and Pauwels.

Applicants submit that since Hudziak doesn't disclose Vinorelbine, and Pauwels fails to provide any guidance on the activity and tolerability of the combination of a HER2 antibody and Vinorelbine in patients, the present claims are patentable over the cited art. Moreover, Applicants rely on unexpected results as demonstrating the nonobviousness of the presently claimed invention. In particular, a press release concerning clinical studies with the combination of an anti-ErbB2/HER2 antibody, Trastuzumab (HERCEPTIN®) and Vinorelbine (NAVELBINE®) in early breast cancer is attached - 29% of evaluable patients experienced a pathologic complete response or the disappearance of all the invasive cancer of the breast, and 93% experienced a clinical response, or shrinkage of the tumor after treatment with HERCEPTIN® and NAVELBINE®. The unexpected results of the presently claimed combination are further discussed in Burstein et al. *J. Clin. Oncol.* 19(10): 2722-2730 (2001) (of record, attached to March 19, 2003 amendment) at the top of column 2 on page 2729 where the response rates achieved with the combination of HER2 antibody and Vinorelbine were said to be higher than expected. See, also, Filipovich et al. *SABCS Meeting Abstract* #436 (2002) (of record, also attached to the March 19, 2003 amendment) which explains that Vinorelbine is one of the drugs with the best combination index with Trastuzumab; and the combination in patients was active and well tolerated.

Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

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Respectfully submitted,  
GENENTECH, INC.

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By: WML  
Wendy M. Lee  
Reg. No. 40,378  
Telephone: (650) 225-1994